

AMENDMENTS TO THE CLAIMS

Claim 1 (Currently Amended): A method of preparing a purified, virus inactivated and virus safe antibody preparation from a starting solution comprising antibodies and contaminants, the method comprising the steps of:

- (a) adjusting the pH of the starting solution to about 4.6 to about 4.95, ~~in particular to about 4.8 to about 4.95~~ to produce an intermediate solution;
- (b) adding caprylate and/or heptanoate ions to the intermediate solution and maintaining the pH at about 4.8 to about 4.95, whereby a precipitate is formed and the antibodies are essentially present in ~~the~~ a supernatant;
- (c) incubating the supernatant solution under conditions of caprylate and/or heptanoate ion concentration, time, pH and temperature and filtering the solution ~~optionally concentrating and diafiltrating the filtrated solution before pH adjustment~~;
- (d) applying the filtered solution ~~with a~~ to at least one anion exchange resin at a pH from about 5.0 to about 5.2 ~~and optionally with two different anion exchange resins~~ under conditions that allow binding of contaminants to the resin while not allowing significant binding of the antibodies to the resin, wherein a purified, virus inactivated and virus safe antibody preparation is produced.

2: Cancelled.

3 (Currently Amended): The method of claim 1 ~~and/or 2 wherein~~ further comprising performing a second anion exchange chromatography is performed at a pH range of from about 6.7 to about 6.9.

4 (Currently Amended): The method of claim 1 ~~claims 1 to 3~~ wherein steps (b) and (c) are repeated at least one time.

5 (Currently Amended): The method of claim 1 ~~claims 1 to 4~~ wherein the starting solution comprises plasma-derived antibodies.

6 (Currently Amended): The method of claim 1 ~~claims 1 to 5~~ wherein ~~in step (d)~~ is performed using the inactivated solution is contacted with two different anion exchange resins under conditions that allow binding of such that contaminants are selectively bound to the resins while the not allowing significant binding of the antibodies, are not significantly bound to the resins.

7 (Currently Amended): The method of claim 1 ~~claims 1 to 6~~, wherein the antibodies are immunoglobulin G.

8 (Currently Amended): The method of claim 6, where the pH is adjusted to about pH 6.8 to 7.4 prior to the second anion-exchange chromatography.

9 (Currently Amended): The method of claim 1 ~~claims 1 to 8~~, ~~wherein~~ further comprising concentrating the anion-exchange chromatography flow-through is concentrated to about 60 to about 90 mg/ml and diafiltrated diafiltrating the anion-exchange chromatography flow-through against a buffer solution, preferably a phosphate buffer.

10 (Currently Amended): The method of claim 1 ~~claims 1 to 9~~, ~~wherein~~ further comprising treating the flow-through of the first anion-exchange chromatography with solvent detergent is solvent detergent treated, preferably by Triton X-100 and TnBP, most preferred by concentrations of 1% Triton X-100 and 0.3% TnBP for about 4.5 to about 8 hours to inactivate lipid coated viruses.

11 (Currently Amended): The method of claim 10, further comprising removing the detergents of the incubation mixture ~~of which are removed~~ by solid and liquid phase extraction.

12 (Currently Amended): The method of at claim 1 ~~least any one of claims 1 to 11 wherein further comprising combining the caprylate treatment with one or more of the following: at least one of the methods selected from the group consisting of UV-C treatment, heat-treatment, virus filtration, and prion removal or inactivation is combined with a caprylate treatment of claim 1.~~

13 (Currently Amended): The method of claim 11, further comprising adjusting ~~wherein~~ the pH value upon solid phase extraction ~~is adjusted~~ to about 6.7 to about 6.9.

14 (Currently Amended): The method of claim 13, further comprising submitting ~~wherein~~ the solution ~~is submitted~~ to the second anion-exchange chromatography.

15 (Currently Amended): The method of claim 14, further comprising adjusting ~~wherein~~ the pH value of the anion-exchanger flow-through ~~is adjusted~~ to about 3.5 to about 4.5, preferably to pH 4.0-4.1.

16 (Currently Amended): The method of claim 15, wherein the antibodies are IgG and further comprising contacting the IgG solution ~~is contacted~~ by a virus filter.

17 (Currently Amended): The method of claim 15, wherein the antibodies are IgG and further comprising contacting the IgG solution ~~is contacted~~ by a nanofilter.

18 (Currently Amended): The method of claim 15 wherein the antibodies are IgG and further comprising incubating the IgG solution ~~is incubated~~ for at least 24 hours, ~~preferably at 37°C~~.

19 (Currently Amended): The method of claim 15, wherein the antibodies are IgG and further comprising concentrating the IgG solution is concentrated to about 5 or about 10% (w/v) to form a concentrate.

20 (Currently Amended): The method of claim 19, wherein the osmolarity of the concentrate is ~~adjusted to~~ about 200 to about 400 mOsmol/kg ~~by an appropriate additive.~~

21 (Currently Amended): The method of claim 20, ~~wherein~~ further comprising adjusting the IgG solution is pH of the IgG solution adjusted to about 3.5 to about 6.0, ~~preferred to a pH value of 4.0 to 5.5.~~

22 (Currently Amended): The method of claim 21 ~~wherein~~ further comprising sterile filtering and filling the IgG solution is sterile filtered and filled in glass bottles or plastic containers.

23 (Currently Amended): An IgG containing fraction produced by the method of claim 1 ~~obtainable according one of the claims 1 to 22.~~

24 (New): The method of claim 9 wherein the buffer solution is a phosphate buffer solution.

25 (New): The method of claim 10 wherein the solvent detergent is Triton X-100 and TnBP.

26 (New): The method of claim 25 wherein the concentration is 1% Triton and 0.3% TnBP.

27 (New): The method of claim 15, wherein the pH is about 4.0.

28. (New): The method of claim 18, wherein the incubation temperature is about 37° C.